

Exhibit 5

In re Zetia (Ezetimibe) Antitrust Litigation

Case No: 2:18-md-2836

Defendants' Presentation on EPP Class Certification Legal Issues

May 1, 2020

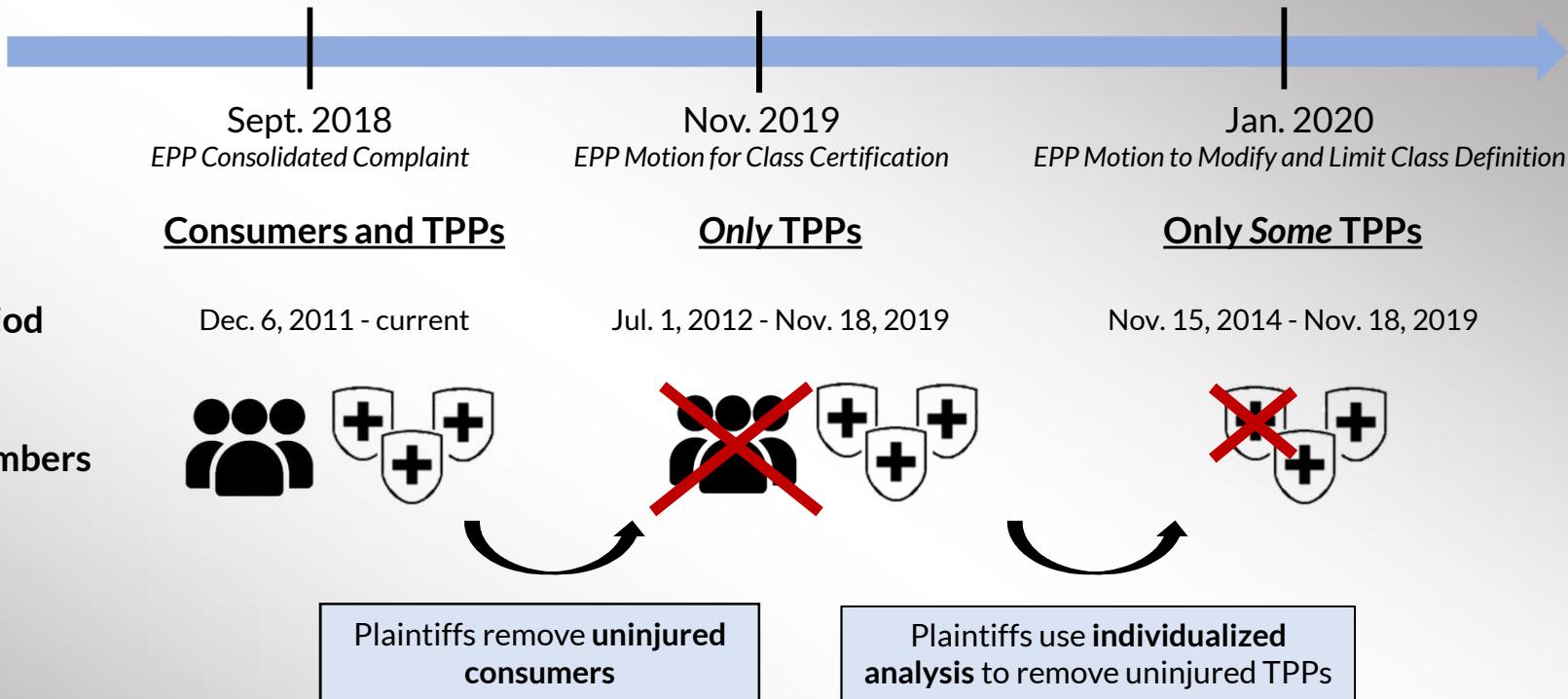
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Outline of Legal Issues

- Shifting Class Definitions
- Legal Standard for Class Certification
- Evidence of Uninjured Class Members
- Ascertainability
- Choice of Law / Variations in State Law

Shifting Class Definitions

EPPs' Continuously Evolving Class Definition Shows That Individualized Inquiry Is Required to Assess Injury



Changes to the Class Definition

- **Nov. 18, 2019:** EPPs drop consumers from the class without explanation but likely in recognition of recent case law suggesting such classes are not viable.¹
- **Jan. 15, 2020:** EPPs radically alter their class definition in the midst of class certification briefing, in light of “further data analysis in connection with the merits expert reports.” EPPs’ Amend Br. at 4.

“All ~~persons and Third-Party Payor~~ entities (“TPPs”) within the Brand Subclass or the Generic Subclass defined herein that, for consumption by their members, employees, insureds, participants, or beneficiaries, and not for resale, indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Zetia or its AB-rated generic equivalents in any form, that was sold through a retail pharmacy, including mail-order pharmacies and long-term care pharmacies, in [the listed states] from ~~July 1, 2012~~ November 15, 2014 (the “but-for generic entry date”) through November 18, 2019.

Brand Subclass: TPPs that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of brand Zetia purchased between the but-for generic entry date and December 11, 2016, inclusive. Excluded from the Brand Subclass are Optum Health Part D Plans, Silverscript Part D Plans, Emblem Health Part D, Humana Part D Plans, Optum Health Managed Care Plans, and any TPPs that used one of these plans or OptumRx as its pharmacy benefits manager (“PBM”) during this subclass period.

Generic Subclass: TPPs that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of generic ezetimibe purchased between the generic entry date (December 12, 2016) and November 18, 2019, inclusive.”

¹ See *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018); *In re Rail Freight Surcharge Antitrust Litig.*, 934 F.3d 619 (D.C. Cir. 2019); *In re Intuniv Antitrust Litigation (Indirect Purchasers)*, 2019 WL 3947262 (D. Mass. Aug. 21, 2019).

Legal Standard for Class Certification

A Class Action Is an Exception, and Plaintiffs Must Prove Its Use Is Appropriate

- The burden of proof at all times is on plaintiffs to prove the requirements of Rule 23.¹
- “Tough questions must be faced and squarely decided, if necessary, by holding evidentiary hearings and choosing between competing perspectives.”²
- When a defendant lodges critiques against plaintiffs’ damages model that is “essential to the plaintiffs’ claim [that] they can offer common evidence of classwide injury,” then “[i]t is [] indisputably the role of the district court to scrutinize th[at] evidence before granting certification.”³

¹ *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350-51 (2011).

² *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 324 (3d Cir. 2008).

³ *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 253 (D.C. Cir. 2013) (emphasis added).

Predominance - Standard

- “Rule 23(b)(3), as an adventuresome innovation, is designed for situations in which class-action treatment is not as clearly called for. . . . [so] the court [has a] duty to take a *close look* at whether common questions predominate over individual ones.”¹
- An antitrust claim has three elements: (1) violation of antitrust law; (2) **injury and causation** (aka “antitrust injury” or “impact”); and (3) damages.²
 - Antitrust cases generally deny certification where plaintiffs have not demonstrated that they can prove **impact** to class members using common proof.

¹ *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013) (emphasis added).

² *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 65 (4th Cir. 1977); *see also In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008).

Recent Circuit Courts Decisions State that “All” or “Substantially All” Class Members Must Be Injured

- **D.C. Circuit:** “[P]laintiffs, to establish predominance, must show that they can prove, through common evidence, that **all class members** were in fact injured by the alleged conspiracy.”¹
- **First Circuit:** “[T]his is a case in which **any class member** may be uninjured, and **there are apparently thousands** who in fact suffered no injury. The need to identify those individuals will predominate....”²
- **Third Circuit:** “[E]very class member must prove at least some antitrust impact resulting from the alleged violation.”³
- **Fifth Circuit:** “[W]e have repeatedly held that where fact of damage [or causation] cannot be established for **every class member** through proof common to the class, the need to establish antitrust liability for individual class members defeats Rule 23(b)(3) predominance.”⁴
- **Sixth Circuit:** Named plaintiffs must show “that they can prove, through common evidence, that **all class members** were in fact injured by the alleged conspiracy.”⁵

¹ *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619, 624 (D.C. Cir. 2019) (emphasis added).

² *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53 (1st Cir. 2018) (emphasis added).

³ *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008) (emphasis added).

⁴ *Bell Atl. Corp. v. AT&T Corp.*, 339 F.3d 294, 302 (5th Cir. 2003) (emphasis added).

⁵ *Rikos v. Proctor &Gamble Co.*, 799 F.3d 497, 522 (6th Cir. 2015) (emphasis added); *see also Food Lion, LLC v. Dean Foods Co.*, 312 F.R.D. 472, 487 (E.D. Tenn. 2016).

The Fourth Circuit Has Endorsed These Recent Decisions

- ***Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 652, 659 (4th Cir. 2019)**
 - Recently, the Fourth Circuit considered the treatment of uninjured class members but did not expressly rule on that basis.
 - The court did, however, expressly acknowledge the recent decisions by the First Circuit in *In re Asacol*¹ and the D.C. Circuit in *In re Rail Freight*² discussing the treatment of uninjured class members, and stated that those decisions were “thoughtful” and “well-reasoned.”
 - It is reasonable to conclude that the Fourth Circuit would follow the reasoning of *Asacol* and *Rail Freight*.

¹ *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018).

² *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619 (D.C. Cir. 2019).

More than a *De Minimis* Number of Uninjured Class Members Defeats Predominance

- *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018)
 - First Circuit stated that where 10% of class members were uninjured, and identifying those members would require individualized inquiry, a class cannot be certified.
- *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d 619 (D.C. Cir. 2019)
 - The D.C. Circuit affirmed the denial of class certification where 12.7% of the class would be uninjured. The court found the raw number yielded approximately 2,000 uninjured members.
- *In re Intuniv Antitrust Litig.*, 2019 WL 3947262 (D. Mass. Aug. 21, 2019)
 - The district court denied class certification where uninjured class members would comprise approximately 8% of the class. Citing *Asacol*, the court considered the raw number of uninjured members (~25,000).
- *In re Thalomid & Revlimid Antitrust Litig.*, 2018 WL 6573118 (D.N.J. Oct. 30, 2018)
 - Shortly after *In re Asacol*, a district court denied class certification where approximately 10% of class members were uninjured.
- *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005 (E.D. Pa. 2015)
 - When at least 5% of the class is uninjured and cannot be identified without individualized inquiry, class certification is not appropriate.

Evidence of Uninjured Class Members

Lamb's Use of Averages Masks a Large Number of Uninjured Class Members

- Dr. Lamb's analysis relies on industry averages and aggregate data that mask individual characteristics of TPPs that lead to no injury:
 - Higher rebates (and PBM rebate guarantees)
 - Placement of Zetia on higher formulary tiers
 - Medicare Part D and government contributions
 - Smaller plans (higher chance of brand loyalty)
- See, e.g., *In re Lamictal Direct Purchaser Antitrust Litig.*, slip op. at 15-16 (3d Cir. Apr. 22, 2020)
 - Finding that the district court could not certify class based on Dr. Lamb's use of "averages" due to the possibility that individual characteristics of purchasers would result in no injury.
 - Noting Dr. Hughes' evidence that Lamb's model "relie[d] on an average hypothetical price, which again fails to account for individual negotiations [and other factors] on each" class member.

EPPs' Theory of Injury Does Not Save the Putative Class

- EPPs wrongly argue that “[a]ntitrust injury occurs ‘the moment the purchaser incurs an overcharge, whether or not that injury is later offset,’ by, for example, a rebate.” EPPs Reply Class Cert. Br. at 6.
- **EPPs' theory of injury does not save the putative class because:**
 - Even applying that erroneous standard, there are still thousands of uninjured class members who did not experience any overcharges.
 - EPPs apply the wrong standard. They must demonstrate that they can show through common proof that substantially all class members suffered net injury to certify their class.

Many TPPs Did Not Experience Overcharges

- EPPs' theory of injury does not impact numerous categories of uninjured class members:
 1. TPPs that existed only in the early portion of the class period (Nov. 2014 to May 2015);
 2. TPPs whose members purchased Zetia only under certain phases of Medicare Part D, since other entities bore all the cost; and
 3. Brand loyal TPPs, whose members would not have purchased generic ezetimibe even if available earlier.
- Moreover, many of the “offsets” that EPPs seek to ignore (i.e., rebates) actually occur “at the exact time of the transaction and not at some later point.”¹

¹ Hughes Declaration ¶ 50.

EPPs Must Demonstrate Net Injury Classwide Through Common Proof

- EPPs wrongly assume demonstrating net injury is not necessary, but many other courts have required plaintiffs to demonstrate that substantially all class members suffered net injury.
 - *Kottaras v. Whole Foods Market, Inc.*, 281 F.R.D. 16, 24-25 (D.D.C. 2012)
 - Denied class treatment, because there was “no way of knowing what percentage of the proposed class ultimately suffered any net injury.”
 - *Exhaust Unlimited, Inc. v. Cintas Corp.*, 223 F.R.D. 506, 513 (S.D. Ill. 2004)
 - Denied class treatment, because “a class member could not have actually been injured unless the alleged conspiracy inflated its net payments.”
 - *Kohen v. Pac. Inv. Mgmt. Co.*, 571 F.3d 672, 678 (7th Cir. 2009)
 - Recognized that “some of the class members probably were net gainers from the alleged manipulation,” but not finding a sufficient number of such net gainers.
- Due to individualized plan characteristics, when netting for gains and losses across the class period, thousands of TPPs would have been worse off financially with earlier generic entry.

State Laws Require Net Injury

- EPPs' authorities focus on federal law principles and fail to appreciate that state indirect purchaser remedies should be interpreted to require actual damages.
- Applicable state laws would likely require proof of actual injury and thus require netting.
 - *A & M Supply Co. v. Microsoft Corp.*, 654 N.W.2d 572, 635 (Mich. Ct. App. 2002)
 - MARA requires “a rigorous analysis” of individual impact because “MARA’s actual damages requirement mandates this approach.”
 - *Kerr v. Abbott*, 1997 WL 314419, at *2, *4 (Minn. Dist. Ct. Feb. 19, 1997)
 - “[D]etermining whether a consumer had been impacted . . . would require the examination of myriad transactions at several levels of distribution to determine applicable dates of purchase, prices, generic substitutes available, and the terms of any rebates or discounts applicable at the time of the transaction.”

Setting Aside “Injury,” EPPs Cannot Prove Net Damages With Common Proof

- Whether referred to as “net injury” or “net damages”, the fact that EPPs cannot use common proof to show that substantially all class members were damaged means that individual issues predominate, especially when combined with the complications and variations of state laws.
- Cf. *Windham v. Am. Brands, Inc.*, 565 F.2d 59 (4th Cir. 1977)
 - Affirming denial of class certification where, among other things, the damages “calculation might be complicated, the district judge found, by the need to allow off-sets against the claims” and finding that “such an offset is appropriate”. *Id.* at 66-67.
 - A court “can and must look at the case as a whole and, as we have seen, consider proof of damages as well as other issues in the case.” *Id.* at 71.

Ascertainability

Ascertainability Legal Authority

- In order for a class to be certified, plaintiffs must also meet the implicit “ascertainability” requirement under Rule 23(a).
 - Plaintiffs bear the burden of meeting “an implicit threshold requirement that the members of a proposed class be ‘readily identifiable.’” This “ascertainability” rule, embedded in Rule 23(a), is only satisfied if EPPs can show that [their] class members are currently and readily identifiable “in reference to objective criteria.”¹
 - “[C]lass litigation should not move forward when a court cannot identify class members without extensive and individualized fact-finding or ‘mini-trials.’”²

¹ *EQT Production Co. v. Adair*, 764 F.3d 347, 358 (4th Cir. 2014); *see also In re A.H. Robins Co.*, 880 F.2d 709, 728 (4th Cir. 1989).

² *Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 658 (4th Cir. 2019).

Exclusions in Current Class Definition

- The court in *Vista Healthplan, Inc. v. Cephalon, Inc.*¹ denied class certification, because the plaintiffs' exclusions "created the need for a structured, multi-stepped, individualized fact-finding process in order to determine which individuals would fall within the class definition and which would fall within one of the eight exclusions."
 - The court found that "Dr. Hughes credibly testified that he was unaware of any administratively feasible approach that would allow Plaintiffs to distinguish class members from persons that fell within an exclusion." *Id.* at *11.
 - The court reasoned that "individual records would need to be compiled to determine whether that person actually belongs within the class, or if they fall within an exclusion." *Id.*

¹ 2015 WL 3623005, at *11 n.14 (E.D. Pa. 2015).

Exclusions in Current Class Definition

- The class definition in *Vista Healthplan* contained 8 exclusions (only 5 of which were relevant to TPPs), whereas here, EPPs' proposed class contains 11 (TPP-only) exclusions, each requiring individual inquiries to identify:

Vista Healthplan Class Exclusions ¹	EPPs' Class Exclusions
(1) Defendants and their subsidiaries and affiliates	
(2) All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans	
(3) All entities that purchased [the brand or generic] for purposes of resale or directly from defendants or their affiliates	
(4) Fully insured health plans	
(5) Pharmacy benefit managers	
(6) Insured <u>individuals</u> under plans imposing a flat copay that was the same dollar amount for generic as for brand purchases	(6) Optum Health Part D Plans
(7) Brand loyal <u>individuals</u>	(7) Silverscript Part D Plans
(8) Insured <u>individuals</u> who purchased only [the generic version] pursuant to a fixed copay applicable to generic drug	(8) Emblem Health Part D Plans
	(9) Humana Part D Plans
	(10) Optum Health Managed Care Plans
	(11) TPPs that used one of these plans or OptumRx as its PBM

¹ See 2015 WL 3623005, at *4.

Choice of Law and Variations in State Law

Choice of Law Analysis

- Courts in the Fourth Circuit recognize that the choice of law analysis is a “complex matter for the moving representatives” by which “predominance is potentially defeated because of the significant manageability problems that can arise.”¹
 - EPPs bear the burden of conducting an adequate choice of law analysis.
 - However, EPPs incorrectly assert that all four transferor jurisdictions “look to the Restatement (Second) of Conflict of Laws for guidance and have adopted flexible approaches that require consideration of all of the relevant policies and interest.”²

¹ *In re Digitek Prod. Liab. Litig.*, 2010 WL 2102330, at *7 (S.D.W. Va. May 25, 2010); *Martin v. Mountain State University, Inc.*, 2014 WL 1333251, at *4–5 (S.D.W. Va. Mar. 31, 2014).

² Memorandum in Support of EPPs’ Motion for Class Certification at 7.

Choice of Law Analysis

- In multi-district litigations, courts apply the choice of law rules of each of the transferor courts.
 - New York applies a governmental interest analysis.¹
 - Virginia applies “the law of the place of the wrong.”²
 - Massachusetts applies the law of the state in which the injury occurred, unless another state has a more significant relationship to the underlying cause of action.³
 - California applies a governmental interest analysis, similar but different from New York’s.⁴

¹ *GlobalNet Financial.Com, Inc. v. Frank Crystal & Co.*, 449 F.3d 377, 384 (2d Cir. 2006).

² *Zurich Am. Ins. Co. v. Pub. Storage*, 743 F. Supp. 2d 525, 535 (E.D. Va. 2010).

³ *Watkins v. Omni Life Sci., Inc.*, 692 F. Supp. 2d 170, 174 (D. Mass. 2010).

⁴ *In re Hyundai & Kia Fuel Econ. Litig.*, 926 F.3d 539, 561 (9th Cir. 2019).

Variations in State Laws

- Defendants identify 26 antitrust, 12 consumer protection, and 26 unjust enrichment state laws after the Court's decision on the motion to dismiss.
- The Fourth Circuit has stated that “[t]he plaintiffs have the burden of showing that common questions of law predominate, and they cannot meet this burden when the various laws have not been identified and compared.”¹
 - EPPs instead try to flip the burden, arguing that “Defendants’ brief fails to explain why the purported variation are material and should defeat predominance.” EPPs’ Reply at 15.

¹ *Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 370 (4th Cir. 2004).

Variations in State Laws

- Numerous courts have denied certification of end-payor classes due to variations in state law.
 - *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946–48 (6th Cir. 2011)
 - *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 591 (9th Cir. 2012)
 - *In re Thalomid & Revlimid Antitrust Litig.*, 2018 WL 6573118, at *1 (D.N.J. Oct. 30, 2018)
 - *Ruffo v. Adidas Am. Inc.*, 2016 WL 4581344, at *1 (S.D.N.Y. Sept. 2, 2016)
 - *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *1 (E.D. Pa. June 10, 2015)
 - *In re Digitek Prod. Liab. Litig.*, 2010 WL 2102330, at *1 (S.D.W. Va. May 25, 2010)